

Bereskin & Parr

INTELLECTUAL PROPERTY LAW

IFW

August 15, 2006



Patricia Folkins B.Sc., Ph.D. (Chem)
416 957 1683 pfolkins@bereskinparr.com

Our Reference: 10935-35

INFORMATION DISCLOSURE STATEMENT

The Commissioner of Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Re: **United States Patent Application No. 10/596,479**
Filed: June 14, 2006
For: METHOD OF TREATING ELEVATED PLASMA HOMOCYSTEINE
LEVELS IN ESRD PATIENTS
Applicant: Bradley L. Urquhart et al.

In accordance with 37 CFR 1.97 and 1.98, and in recognition of the duty of disclosure set forth in 37 CFR 1.56, Applicants hereby submit an Information Disclosure Statement on Form PTO-1449 containing a listing of patents and other publications of which Applicant is aware. Applicants are also submitting the references listed on the Supplemental Information Disclosure Statement.

All of the patents and publications submitted herewith are in the English language. Accordingly a concise explanation of the relevance of the documents is not required.

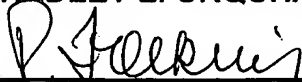
The Examiner is requested to indicate consideration of these documents by initialing the appropriate column.

Applicants reserve the right to contest the applicability of any of these documents as prior art against the subject application. If the Examiner has any questions concerning this Information Disclosure Statement, he/she is requested to contact the undersigned. Entry of the enclosed Information Disclosure Statement is believed to be in order and is respectfully requested.

This Information Disclosure Statement is being filed before the issuance of a first official action, and therefore no fees are required. However, please charge our deposit account No. 02-2095 if such a fee is required.

Respectfully submitted,

BRADLEY L. URQUHART

A handwritten signature in cursive script, appearing to read 'P. Folkins', is written over a horizontal line.


Patricia Folkins

Registration No. 51,379

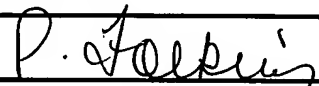
Dated: August 15, 2006

Bereskin & Parr
Box 401, 40 King Street West
Toronto, Ontario, Canada
M5H 3Y2

(416) 364-7311

TRANSMITTAL FORM  (to be used for all correspondence after initial filing)	Application Number	10/596,479	
	Filing Date	June 14, 2006	
	First Named Inventor	Bradley L. Urquhart et al.	
	Art Unit	N/A	
	Examiner Name	N/A	
Total Number of Pages in This Submission	5	Attorney Docket Number	10935-35

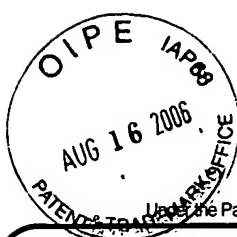
ENCLOSURES (check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer x 2 <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Letter
Remarks 		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT			
Firm	Bereskin & Parr		
Signature			
Printed Name	Patricia Folkins		
Date	August 15, 2006	Reg. No.	51,379

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08b(08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/596,479
Filing Date	June 14, 2006
First Named Inventor	Bradley L. Urquhart
Art Unit	N/A
Examiner Name	N/A
Attorney Docket Number	10935-35

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1.	FINKELSTEIN, J. D., "The metabolism of homocysteine: pathways and regulation", Eur J Pediatr, 1998, pp. S40-S44, Vol. 157, No. 2.	
	2.	CHAO, Chia-Lun, et al., "The graded effect of hyperhomocysteinemia on the severity and extent of coronary atherosclerosis", Atherosclerosis, 1999, pp. 379-386, Vol. 147.	
	3.	SPENCE, J. David, et al., "Plasma homocyst(e)ine concentration, but not MTHFR genotype, is associated with variation in carotid plaque area", Stroke, 1999, pp. 969-973, Vol. 30.	
	4.	VASAN, Ramachandran S., et al., "Plasma homocysteine and risk for congestive heart failure in adults without prior myocardial infarction", JAMA, 2003, pp. 1251-1257, Vol. 289, No. 10.	
	5.	UBBINK, Johan B., et al., "Vitamin requirements for the treatment of hyperhomocysteinemia in humans" Human and Clinical Nutrition, 1994, pp. 1927-1933, Vol. 124.	
	6.	HACKAM, Daniel G., et al., "What level of plasma homocyst(e)ine should be treated? Effects of vitamin therapy on progression of carotid atherosclerosis in patients with homocyst(e)ine levels above and below 14 µmol/L", American Journal of Hypertension, 2000, pp.105-110, Vol. 13, No. 1.	
	7.	ANWAR, Wafaa, et al., "Hyperhomocysteinemia is related to residual glomerular filtration and folate, but not to methylenetetrahydrofolate-reductase and methionine synthase polymorphisms, in supplemented end-stage renal disease patients undergoing hemodialysis", Clin Chem Lab Med, 2001, pp. 747-752, Vol. 39, No. 8.	
	8.	ARNADOTTIR, M., et al., "The effect of reduced glomerular filtration rate on plasma total homocysteine concentration", Scand J Clin Lab Invest, 1996, pp. 41-46, Vol. 56.	
	9.	HOUSE, Andrew, et al., "Effect of multivitamins on plasma homocysteine levels in patients on heodialysis", ASAIO Journal, 1999, pp.94-97, Vol. 45.	
	10.	SPENCE, J. David, et al., "Effect of usual doses of folate supplementation on elevated plasma homocyst(e)ine in hemodialysis patients: no difference between 1 and 5 mg daily", Am J Nephrol, 1999, pp. 405-410, Vol. 19	
	11.	ELIAN, Kelly M., et al., "Hydroxocobalamin reduces hyperhomocysteinemia in end-stage renal disease", Metabolism, 2002, pp. 881-886, Vol. 51, No. 7.	
	12.	BOSTOM, Andrew G., et al., "Short term betaine therapy fails to lower elevated fasting total plasma homocysteine concentrations in hemodialysis patients maintained on chronic folic acid supplementation", Atherosclerosis, 1995, pp. 129-132, Vol. 113.	
	13.	HOUSE, Andrew, et al., "Randomized trial of high-flux vs low-flux haemodialysis: effects on homocysteine and lipids", Nephrology Dialysis Transplantation, 2000, pp. 1029-1034, Vol. 15.	
	14.	VRIESE, An S., et al., "Effect of dialyser membrane pore size on plasma homocysteine levels in haemodialysis patients", Nephrology Dialysis Transplantation, 2003, pp.2596-2600, Vol. 18.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/SB/08b(08-03)

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known			
		Application Number	10/596,479		
		Filing Date	June 14, 2006		
		First Named Inventor	Bradley L. Urquhart		
		Art Unit	N/A		
		Examiner Name	N/A		
Sheet	2	of	3	Attorney Docket Number	10935-35

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	15.	FRIENDMAN, Allon N., et al., "The effect of N-acetylcysteine on plasma total homocysteine levels in hemodialysis: a randomized, controlled study", American Journal of Kidney Diseases, 2003, pp. 442-446, Vol. 41, No. 2.	
	16.	VENTURA, Paolo, et al., "Urinary and plasma homocysteine and cysteine levels during prolonged oral N-acetylcysteine therapy", Pharmacology, 2003, pp. 105-114, Vol. 68.	
	17.	LAUTERBURG, Bernhard, et al., "Depletion of total cysteine, glutathione, and homocysteine in plasma by ifosfamide/mesna therapy", Cancer Chemother Pharmacol, 1994, pp. 132-136, Vol. 35.	
	18.	PENDYALA, Lakshmi, et al., "Intravenous ifosfamide/mesna is associated with depletion of plasma thiols without depletion of leukocyte glutathione", Roswell Park Cancer Institute, 2000, pp.1314-1321, Vol. 6.	
	19.	PENDYALA, Lakshmi, et al., "Modulation of plasms thiols and mixed disulfides by BNP7787 in patients receiving paclitaxel/cisplatin therapy", Cancer Chemother Pharmacol, 2003, pp. 376-384, Vol. 51.	
	20.	JACOBSEN, Donald W., et al., "Rapid HPLC determination of total homocysteine and other thiols in serum and plasma: sex differences and correlation with cobalamin and folate concentrations in healthy subjects", Clin. Chem., 1994, pp. 873-881, Vol. 40, No. 6.	
	21.	BOSTOM, Andrew G., et al., "Hyperhomocysteinemia and traditional cardiovascular disease risk factors in end-stage renal disease patients on dialysis: a case-control study", Atherosclerosis, 1995, pp. 93-103, Vol. 114.	
	22.	BOSTOM, Andrew G., "Homocysteine: "expensive creatine" or important, modifiable risk factor for arteriosclerotic outcomes in renal transplant recipients?", J Am Soc of Nephrol, 2000, pp. 149-151, Vol. 11.	
	23.	DUCLoux, Didier, et al., "Hyperhomocysteinaemia therapy in haemodialysis patients: folinic versus folic acid combination with vitamin B6 and B12", Nephrol Dial Transplant, 2002, pp. 865-870, Vol. 17.	
	24.	SIGIT, Joseph I., et al., "Total plasma homocysteine and related amino acids in end-stage renal disease (ESRD) patients measured by gas chromatography-mass spectrometry – comparison with the abbott IMx homocysteine assay and the HPLC method", Clin Chem Lab Med, 2001, pp. 681-690, Vol. 39, No. 8.	
	25.	SORIA, C., et al., "Concentrations of total homocysteine in plasma in chronic renal failure", Clinical Chemistry, 1990, pp.2137-2138, Vol. 36, No. 12.	
	26.	SQUID, Abdul-Kader, et al., "Blood thiols following amifostine and mesna infusions, a pediatric oncology group study", The American Society for Pharmacology and Experimental Therapeutics, 2001, pp. 1460-1466, Vol. 29.	
	27.	YAMAMOTO, Nobuko, et al., "Effect of cysteine on expression of cystathionine β -synthase in the rat liver", J. Nutr. Sci. Vitaminol., 1995, pp. 197-205, Vol. 41.	
	28.	GOREN, Marshal P., et al., "Reduction of dimesna to mesna by the isolated perfused rat liver", Cancer Research, 1998, pp. 4358-4362, Vol. 58.	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

<i>Application Number</i>	10/596,479
<i>Filing Date</i>	June 14, 2006
<i>First Named Inventor</i>	Bradley L. Urquhart
<i>Art Unit</i>	N/A
<i>Examiner Name</i>	N/A
<i>Attorney Docket Number</i>	10935-35

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.